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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/722,971	11/25/2003	Junyu Mai	A00P1029US01	9049

36802 7590 06/07/2005

PACESETTER, INC.
15900 VALLEY VIEW COURT
SYLMAR, CA 91392-9221

EXAMINER	
EVANISKO, GEORGE ROBERT	
ART UNIT	**PAPER NUMBER**
3762	

DATE MAILED: 06/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/722,971	MAI ET AL.	
	Examiner	Art Unit	
	George R Evanisko	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 November 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-9* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received..

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *11/25/03*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Priority

This application repeats a substantial portion of prior Application No. 09/627528, filed 7/28/00, and adds and claims additional disclosure not presented in the prior application. Since this application names an inventor or inventors named in the prior application, it constitutes a continuation-in-part of the prior application. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78. The subject matter not described in the original specification, 09/6275287, is the limitation of selecting "an atrioventricular delay based solely on the sensed posture of the patient". To the contrary, cancelled claims 28 and 32 in the parent case, 09/627528, figures 1 and 2, page 16, paragraph 62, and page 9, lines 1 and 2 of the specification clearly disclose that the AV delay is varied with the sensed activity or pacing rate of the patient. Further, figure 3 and page 14, paragraph 54 disclose varying the AV delay dependent on detection of a new cardiac cycle (see MPEP 2173.05(i)). See MPEP 201.11 VI and 602.05(a).

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

> The oath or declaration is defective because: the case contains new claimed subject matter of basing the AV delay "solely" on the sensed posture, which was not found in the original disclosure of the parent case, 09/627528,. Therefore the claimed subject matter is not encompassed by the original parent disclosure.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Varying the "pacing rate" based on the activity sensor is not described in the summary, abstract, description, or background of the specification. In addition, the specification has not stated that the AV delay can be based "solely" on the sensed posture.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later

invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 2, 4, 5, 7, and 8 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Florio et al (6259948). Florio discloses the use of his system to adjust the AV delay using only one sensor (column 2, line 8, and column 4, line 20), the sensor being a position/posture sensor (column 4, line 43 and claims 5 and 12) determining erect from supine (column 4, lines 44-45), and increasing the AV delay based on inactivity and decreasing the AV delay based on activity. In addition, it is inherent that the activity is due to being erect from a supine position and the inactivity is due to being supine from the erect position when a position sensor is used. Florio also teaches altering the AV delay based on the sensor (column 3, line 37) and it is inherent that the AV delay is increased when going form an upright to lying position and decreased when going from a lying to upright position since any other way would go against the natural heart rate of a person when changing posture positions.

In the alternative, Florio discloses the claimed invention except for the increase of the AV delay when going from an upright to lying position and the decrease of the AV delay when going from a lying to upright position. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the IMD having AV adjustment based on position as taught by Florio, with the increase of the AV delay when gong from an upright to lying position and the decrease of the AV delay when going from a lying to upright position since it was known in the art the IMDs using position sensors adjust the pacing interval, such as A-A, V-V, V-A, and A-V, to increase when going from the upright to lying position and to

decrease when going from the lying to upright position, to provide an IMD that generates pacing pulses according to the physical position of the patient, in a manner and at a value, level, or magnitude which most closely approximates the actual heart rate of a healthy person with a normal cardiovascular system who has assumed that position, and, further, at a rate which is appropriate for the patient in question.

Claims 3, 6, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Florio et al. Florio discloses all the claimed limitations but does not explicitly speak to adjusting the pacing rate based on sensed activity from a separate activity sensor. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the pacemaker with a variable pacing rate having a posture detector which, in combination with other sensors, adjusts the pacing rate, of Florio to include an activity sensor since it was well known in the art to include activity sensors in pacemakers for distinguishing between slowly varying activity states, like sleep, from more rigorous activity periods and applying a pacing therapy accordingly so as to conserve battery power in the implantable pacing device and not provide the patient with unnecessary and potentially harmful stimulation.

Claims 1-9 are rejected under 35 U.S.C. 102(e) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Pianca et al (6466821). Pianca states in column 10 that the AV delay is shortened when the patient in known to be standing and therefore uses only position to adjust the AV delay and inherently will increase the AV delay when going from an upright to lying position and decrease the AV delay when going from a lying to upright position.

In the alternative, Pianca discloses the claimed invention except for the increase of the AV delay when going from an upright to lying position and the decrease of the AV delay when

going from a lying to upright position. It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the IMD having AV adjustment based on position as taught by Pianca, with the increase of the AV delay when gong from an upright to lying position and the decrease of the AV delay when going from a lying to upright position since it was known in the art the IMDs using position sensors adjust the pacing interval, such as A-A, V-V, V-A, and A-V, to increase when going from the upright to lying position and to decrease when going from the lying to upright position, to provide an IMD that generates pacing pulses according to the physical position of the patient, in a manner and at a value, level, or magnitude which most closely approximates the actual heart rate of a healthy person with a normal cardiovascular system who has assumed that position, and, further, at a rate which is appropriate for the patient in question.

Claims 3, 6, and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Florio et al. Florio discloses all the claimed limitations but does not explicitly speak to adjusting the pacing rate based on sensed activity from a separate activity sensor. It would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the pacemaker with a variable pacing rate having a posture detector which, in combination with other sensors, adjusts the pacing rate, of Florio to include an activity sensor since it was well known in the art to include activity sensors in pacemakers for distinguishing between slowly varying activity states, like sleep, from more rigorous activity periods and applying a pacing therapy accordingly so as to conserve battery power in the implantable pacing device and not provide the patient with unnecessary and potentially harmful stimulation.

Conclusion

This is a continuation (continuation in part) of applicant's earlier Application No. 09/627528. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to George R Evanisko whose telephone number is 571 272 4945. The examiner can normally be reached on M-F 6:30-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on 571 272 4955. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

George R Evanisko
Primary Examiner
Art Unit 3762
5/12/5

GRE
May 12, 2005